OCT 2 6 2012

ACUSON X700 ™ Ultrasound System 510(k) Submission

510(k) Summary Prepared August 22, 2012

Sponsor:

Siemens Medical Solutions, Inc.,

Ultrasound Division

685 East Middlefield Road Mountain View, California 94043

Contact Person:

Shelly Pearce

Telephone:

(650) 694-5988

Fax:

(650) 694-5580

Device Name:

ACUSON X700[™] Ultrasound System

Common Name:

Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: Review Category:

Ш Tier II

Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer Diagnostic Intravascular Catheter

FR # 892.1560 FR # 892.1570

Product Code 90-IYN Product Code 90-IYO Product Code 90-ITX

FR # 870.1200

Product Code OBJ

A. Legally Marketed Predicate Devices

The Siemens ACUSON X700[™] Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens ACUSON X300 ultrasound system (K121699), ACUSON S2000 ultrasound system (K112596) and Ultrasonix SonixTABLET ultrasound scanner (K113663, K102997).

B. Device Description:

The Siemens ACUSON X700[™] is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M mode, Tissue Doppler Image, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

C. Intended Use

The Siemens ACUSON X700[™] ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients

D. Substantial Equivalence

The Acuson X700 is substantially equivalent to the Acuson X300, cleared via K121699, and Acuson S2000, cleared via K112596 and SonixTABLET ultrasound scanner cleared via K113663. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2

- EN/IEC 60601-1-4
- EN/IEC 60601-1-6
- EN/IEC 60601-2-18
- EN/IEC 60601-2-25
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

F. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the X700 uses the same technology and principles as existing devices, clinical data is not required.

G. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the X700 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The Acuson X700 is verified and validated according to the company's design control process.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

OCT 2 6 2012

Siemens Medical Solutions USA, Inc. – Ultrasound Group % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K123001

Trade/Device Name: Acuson X700™ Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX, and OBJ

Dated: September 26, 2012 Received: September 27, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson X700TM Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C1 Curved Array
VF10-5 Linear Array
VF12-4 Linear Array
EC9-4w Convex Array
6C2 Curved Array
CW2
CW5
AcuNav 8F Intracardiac
AcuNav 10F Intracardiac

V5Ms TEE

4V1c Phased Array
C7F2 Curved Array
EV9F4 Curved Array
SoundStar 10F
SoundStar eco 10F

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Janine M. Morris

Director

Division of Radiological Health Office of In Vitro Diagnostics and Radiological Health

Center for Devices and Radiological Health

Enclosure(s)

Tab 1.3.1 Indications for Use Forms

Indications for Use Statement

Office of In Vitro Diagnostic Devices

Device Name: ACUSON X700™ Diagnostic Ultrasound System Indications For Use: The Siemens ACUSON X700™ ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications. The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physican with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. Prescription Use X Androw Androw Over-The-Counter Use (21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	
Indications For Use: The Siemens ACUSON X700™ ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications. The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. Prescription Use X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)	510(k) Number (if known):
The Siemens ACUSON X700 TM ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications. The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with a reasily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. Prescription UseX AND/OR	Device Name: ACUSON X700 [™] Diagnostic Ultrasound System
The Siemens ACUSON X700 TM ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications. The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. Prescription UseX AND/OR	
applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications. The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Indications For Use:
The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. Prescription Use X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-
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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)	(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
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Page 1 of _____

510(k) Number (if known):

Device Name: Intended Use:

ACUSON X700 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation										
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic											
	Fetal	Р	Р	Р	Р	₽	Ρ.	BMDC	Note 2,3,4,5,6,9,10,12,19,21			
	Abdominal	Р	Р	Р	Р	Р	Р	BMDC	Note 2,3,4,6,9,10,11,20			
	Intra-operative (Note 6)	P	Р	Р	Р	Р	Р	вмос	Note 2,3,4,6,9,10			
	Intra-operative (Neuro)											
	Laparoscopic	-	ļ									
Fetal	Pediatric	Р	Р	Р	Р	Р	P	BMDC	Note 2,3,4,6,9,10,11			
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р	Р	Р	Р	BMDC	Note 2,3,4,5,6,9,10,11,19			
	Neonatal Cephalic	Р	Р	Р	P	Р	Р	BMDC	Note 2,3,4,5,9,10,11			
	Adult Cephalic	Ρ	P	Р	P	Р	Р	BMDC	Note 2,3,4,9,10,11			
	Trans-rectal	Р	Р	Р		Р	Р	BMDC	Note 2,3,4,5,9,10,19			
	Trans-vaginal	Р	Р	Р		Ρ	Р	BMDC	Note 2,3,4,5,9,10,12,19, 21			
•	Trans-urethral		-									
	Trans-esoph. (non-Card.)											
	Musculo-skel. (Convent.)	Р	Р	Р		P	Р	вмос	Note 2,3,4,9,10,11			
	Musculo-skel. (Superfic)	Р	Р	Р		Р	Р	BMDC	Note 2,3,4,9,10,11			
	Intra -vascular	Р	Р	Р	Р	Р	P	BMDC	Note 2,8,9,13,14,15,16			
	Other (Specify)											
	Cardiac Adult	Р	Р	Р	P	Р	P	BMDC	Note 2,7,8,9, 13, 14,15,16,17,18,19			
Cardiac	Cardiac Pediatric	Р	P	Р	Р	Р	P	BMDC	Note 2,3,4,6,8,9,10,13,14,15,16			
	Intra-vascular (Cardiac)	Р	P	Р	Р	Р	Р	BMDC	Note 2,8,9,13,14,15,16			
	Trans-esophageal (Cardiac)	Р	Р	Р	Р	Р	Р	вмос	Note 2,7,9,14,17,18,19			
	Intra-Cardiac	Р	Р	Р	Р	P	Р	BMDC	Note 2,8,9,13,14,15,16			
	Other (Specify)	1	<u> </u>									
Peripheral	Peripheral vessel	Р	Р	Р	Р	Р	Р	BMDC	Note 2,3,4,6,9,10,11			
Vessel	Other (Specify)											

N = new indication; P = previously cleared by K121699, K112596

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
	• • •	Note 21	syngo Auto follicle

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Division Sign-Off - Office of I	n vitro Diagnostic Devices			
510(k) / / / C	<u>) (</u>			

510(k) Number (if known):

Device Name:

Intended Use:

4C1 Curved Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Appli	cation	Mod	e of Op	peration					
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р	Р	Р	Р	BMDC	Note 2,3,4,5,6,9,10,12
	Abdominal	P	Р	Р_	Р	Р	Р	вмос	Note 2,3,4,6,9,10, 20
	Intra-operative (Note 6)	Р	Р	Ρ,	Р	Р	Р	вмос	Note 2,3,4,6,9,10
	Intra-operative (Neuro)			·					
	Laparoscopic	ļ	ļ		<u> </u>			<u> </u>	
Fetal	Pediatric						,		
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р	P	Р	Р	BMDC	Note 2,3,4,6,9,10
	Neonatal Cephalic								
	Adult Cephalic	1							
	Trans-rectal-1					1			
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
•	Musculo-skel. (Convent.)					[
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								····
	Cardiac Adult								
Cardiac	Cardiac Pediatric		<u> </u>						
	Intra-vascular (Cardiac)								•
	Trans-esophageal (Cardiac)								
	Intra-cardiac	1						1	
	Other (Specify)								
Peripheral	Peripheral vessel	Р	Р	Р	Р	Р	. Р	BMDC	Note 2,3,4,6,9,10
Vessel	Other (Specify)								

N = new indication; P = previously cleared by K112596

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Artenai Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
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Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
	· · · · · · · · · · · · · · · · ·	Note 21	syngo Auto follicle

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Division Sign-Off - Office of In Vitro Diagnostic Devices	
510(k) K/2300/	Page 3 of

510(k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with: **ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD	Color Doppier	Power Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic		i					,			
	Fetal										
						-					
	Abdominal	Р	Р	Р		Р	P	BMDC	Note 2,3,4,9,10,11		
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic							<u> </u>			
Fetal	Pediatric	Р	P	P		P	P	BMDC	Note 2,3,4,9,10,11		
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	P	BMDC	Note 2,3,4,9,10,11		
	Neonatal Cephalic	Р	Р	Р		Р	Р	BMDC	Note 2,3,4,9,10,11		
	Adult Cephalic	P	P	Р	 	Р	Р	BMDC	Note 2,3,4,9,10,11		
	Trans-rectal	1									
	Trans-vaginal										
	Trans-urethrai										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	P	Р	Р		Р	P	BMDC	Note 2,3,4,9,10,11		
	Musculo-skel. (Superfic)	Р	Р	Р		Р	Р	BMDC	Note 2,3,4,9,10,11		
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult	<u> </u>									
Cardiac	Cardiac Pediatric							<u> </u>			
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)		ļ		ļ						
	Intra-cardiac	<u> </u>	<u> </u>	ļ	 	ļ		 			
	Other (Specify)	_			<u> </u>						
Peripheral	Peripheral vessel	Р	Р	Р	<u> </u>	P	Р	BMDC	Note 2,3,4,9,10,11		
Vessel	Other (Specify)	i			1			1			

syngo Arterial Health Package (AHP) syngo Auto OB Measurements syngo Auto Left Heart (Auto LH) Technology For example: breast, testes, thyroid, penis, prostate, etc. Dynamic TCE Technology Note 1 Note 11 Note 2 Note 12 Note 3 SieClear Note 13 syngo Velocity Vector Imaging Technology Note 4 Advanced SieClear Note 14 Note 5 3-Scape 3D Imaging Note 15 CartoSound Communication Note 6 For example: abdominal, vascular Note 16 Intracardiac Echocardiography (ICE) Imaging Stress Echo Imaging
Axius Edge Assisted Ejection Fraction
Clarify Vascular Enhancement Technology
SieScape Panoramic Imaging Note 7 Note 17 syngo fourSight TEE View Note 18 syngo Mitral Valve Assessment (MVA) Note 8 Note 19 syngo fourSinght 4D imaging Note 9 Note 10

Contrast Agent Imaging Note 20 Note 21 syngo Auto follicle

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510(k) Number (if known):

Device Name:

VF12-4 Linear Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Intended Use:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1I& 3)	В	м	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	N	N	N	ļ.	א	N	BMDC	Note 2,3,4,9,10,11
Imaging & Other	SmallOrgan (Note 1)	N	N	N		N	N	вмос	Note 2,3,4,9,10,11
	Neonatal Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Adult Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								• •
	Musculo-skel. (Convent.)	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Musculo-skel. (Superfic)	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Intra-vascular Other (Specify)				· · · · · · · · · · · · · · · · · · ·	:			
	Cardiac Adult							1	
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								,
	Intra-cardiac					_			
	Other (Specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
Vessel	Other (Specify)								

N = new indication; P = previously cleared

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
	· ·	Note 21	syngo Auto follicle

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510(k) Number (if known):

Device Name:

EC9-4w Convex Array Transducer for use with:
ACUSON 7300 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Intended Use:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1I& 3)	В	м	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12, 21
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric					-		T	
Imaging & Other	SmallOrgan (Note 1)	N	N	N		N	N	BMDC	Note 2,3,4,5,9,10
	Neonatal Cephalic	N	N	N		И	N	BMDC	Note 2,3,4,5,9,10
	Adult Cephalic								
	Trans-rectal	N .	N	N		N	N	BMDC	Note 2,3,4,5,9,10
	Trans-vaginal	. N	N	N		N	N	BMDC	Note 2,3,4,5,9,10,12, 21
	Trans-urethral								
	Trans-esoph. (non-Card.)		,						
	Musculo-skel. (Convent.)								· · · · · · · · · · · · · · · · · · ·
	Musculo-skel. (Superfic)								
	Intra-vascular							ļ l	
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)				,				
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared

Note 1	roi example, breast, testes, triyroid, penis, prostate, etc.	MOLETT	syngo Arienai nealth Fackage (AnF)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
	·	Note 21	syngo Auto follicle

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510(k) K/23001	•	•	

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510(k) Number (if known):

Device Name:

6C2 Curved Array Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
Other (Track1 Only)	Specific (Tracks1I& 3)	В	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal	Р	Р	P	Р	Р	P	вмос	Note 2,3,4,5,6,9,10,12	
	Abdominal	Р	Р	Р	Р	Р	Р	BMDC	Note 2,3,4,6,9,10	
	Intra-operative (Note 6)	Р	P	P	Р	Р	Р	BMDC	Note 2,3,4,6,9,10	
	Intra-operative (Neuro)									
	Laparoscopic					ļ <u> </u>		 		
Fetal	Pediatric	Р	Р	P	Р	P	Р	вмос	Note 2,3,4,6,9,10	
Imaging & Other	SmallOrgan (Note 1)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal					1				
	Trans-vaginal	Î	Ī							
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)							1		
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult					ļ <u> </u>				
Cardiac	Cardiac Pediatric	Р	Р	P	Р	Р	Р	BMDC	Note 2,3,4,6,9,10	
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)					ļ <u> </u>				
	Intra-cardiac		L_		<u> </u>	<u> </u>	<u> </u>	 		
	Other (Specify)				<u> </u>	ļ		`		
Peripheral	Peripheral vessel	Р	Р	P	Р	Р	Р	BMDC	Note 2,3,4,6,9,10	
Vessel	Other (Specify)					1				

N = new indication; P = previously cleared K112596

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
	, , ,	Note 21	syngo Auto follicle

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Device Name:

CW2 Continuous Wave Doppler Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
,	Fetal				P				
	Abdominal				P				
	Intra-operative (Note 6)				Р		·		
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric				.P				
Imaging & Other	SmaliOrgan (Note 1)				Р			-	<u> </u>
	Neonatal Cephalic				Р				
	Adult Cephalic				P			<u> </u>	
	Trans-rectal				·				
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular Other		<u> </u>					-	
	(Specify)								
	Cardiac Adult	Ī			Р				
Cardiac	Cardiac Pediatric				Р				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	_							
	Other (Specify)				<u> </u>	<u></u>	L		
Peripheral	Peripheral vessel				Р				
Vessel	Other (Specify)								

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
		Note 21	syngo Auto follicle

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Device Name:

CW5 Continuous Wave Doppler Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal				P				
	Abdominal				Р				
	Intra-operative (Note 6)			-	Р		- 1.::		" "
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric				P				
Imaging & Other	SmallOrgan (Note 1)				P				
	Neonatal Cephalic				Р				
	Adult Cephalic				, Р				
	Trans-rectal	1							
	Trans-vaginal								
	Trans-urethral	†					""		
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular Other (Specify)								
*	Cardiac Adult	Ī			Р				
Cardiac	Cardiac Pediatric	1	<u> </u>		Р		<u> </u>		
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)							,	
	Intra-cardiac	<u> </u>				<u> </u>			
	Other (Specify)	<u> </u>		<u> </u>	1				
Peripheral	Peripheral vessel				Р				
Vessel	Other (Specify)			1					

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
	,	Note 21	syngo Auto follicle

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Device Name:

AcuNav 8F Intracardiac Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 . Only)	Specific (Tracks1I& 3)	В	м	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	,							
	Abdominal						<u> </u>		
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic	i							
	Trans-rectal							•	
	Trans-vaginal								<u> </u>
	Trans-urethral							ļl	
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)		İ						· _
	Intra-vascular	Р	Р	Р	Р	Р	Р	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
	Cardiac Adult	Р	Р	Р	Ρ.	P	Р	BMDC	Note 2,8,9,13,14,16
Cardiac	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	BMDC	Note 2,8,9,13,14,16
	Intra-vascular (Cardiac)	Р	Р	Р	Р,	Р	Р	вмос	Note 2,8,9,13,14,16
	Trans-esophageal (Cardiac)								·
	Intra-cardiac	P	P	P	Р	P	Р	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)	1		<u> </u>		1			

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Artenai Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
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Device Name:

AcuNav 10F Intracardiac Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD .	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal								30301	
	Intra-operative (Note 6)									
•	Intra-operative (Neuro)									
	Laparoscopic						<u>. </u>	<u> </u>		
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)									
	Neonatal Cephatic									
	Adult Cephalic	1 -								
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral				_					
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	<u> </u>				ļ				
	Musculo-skel. (Superfic)	<u> </u>								
	Intra-vascular	Р	P	Р	P ,	P	Р	BMDC	Note 2,8,9,13,14,16	
	Other (Specify)	l								
-	Cardiac Adult	Р	Р	Р	P	Р	Р	BMDC	Note 2,8,9,13,14,16	
Cardiac	Cardiac Pediatric	P	Р	Р	Р	Р	P	BMDC	Note 2,8,9,13,14,16	
	Intra-vascular (Cardiac)	Р	Р	Ρ	Р	Р	Р	BMDC	Note 2,8,9,13,14,16	
	Trans-esophageal (Cardiac)									
	Intra-cardiac	Р	Р	Р.	Р	Р	Р	вмос	Note 2,8,9,13,14,16	
	Other (Specify)									
Peripheral	Peripheral vessel	1	<u> </u>							
Vessel	Other (Specify)	T	1				1			

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Artenal Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
		Note 21	syngo Auto follicle

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510(k) Number (if known):

Device Name:

V5Ms TEE Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal							-	
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic				_				
Fetal	Pediatric								
Imaging & Other	SmalfOrgan (Note 1)								<u></u>
	Neonatal Cephalic								-
	Adult Cephalic	1							
	Trans-rectal			-				<u>.</u>	
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)				<u> </u>				
	Musculo-skel. (Superfic)	<u> </u>	<u>.</u>						
	Intra-vascular Other	 			<u> </u>	ļ			
	(Specify)							l	
	Cardiac Adult	Р	Р	Р	Р	Р	Р	BMDC	Note 2,7,9,14,17,18,19
Cardiac	Cardiac Pediatric	1							
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)	Р	Р	Р	Р	Р	Р	BMDC	Note 2,7,9,14,17,18,19
	Intra-cardiac	1		<u> </u>	ļ	ļ		 	
	Other (Specify)	ļ	<u> </u>			<u> </u>			
Peripheral	Peripheral vessel	1	L			ļ	<u> </u>		
Vessel	Other (Specify)		<u> </u>			<u></u>	<u> </u>		

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arteriai Health Package (ARP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
		Note 21	syngo Auto follicle

	
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Pivision Sign-Off - Office of In Vitro Diagrostic Devices	
Mivision Sign-Off - Office of In Vitro Diagnostic Devices	
510(k) K123001	Page 12 of

510(k) Number (if known):

Device Name:

4V1c Phased Sector Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Intended Use:

Clinical Appli	Mode of Operation								
Other (Track1 Only)	Specific (Tracks1I& 3)	В	м	P.WD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р		Р	Р	BMDC	Note 2,9
	Abdominal	Р	P	Р		Р	Р	BMDC	Note 2,9
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
Fetal	Laparoscopic Pediatric								
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic	Р	Р	P	P	Р	Р	BMDC	Note 2,9
	Adult Cephalic	Р	Р	₽	Р	Р	P	BMDC	Note 2,9
	Trans-rectal		i —						
	Trans-vaginal					1			
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)						·-		
	Intra-vascular							<u> </u>	
	Other (Specify)				ļ				
	Cardiac Adult	Р	P	Р	Р	Р	Р	BMDC	Note 2,7,8,9, 13, 14
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arteriai Health Package (ARP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
		Note 21	syngo Auto follicle

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Dision Sigh-Off - Office of In Vitro Diag	ostic Devices	
510(k) K123 <i>001</i>	•	

510(k) Number (if known):

Device Name:

C7F2 Curved Array Mechanical 3D/4D Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1I& 3)	В	м	PWD	CWD	Color Doppler	Power . Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р	Р	Р	Р	вмос	Note 2,3,4,5,6,9,10,12,19
	Abdominal	Р	Р	Р	P	Р	P	вмос	Note 2,3,4,6,9,10
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic				ļ	ļ			
Fetal	Pediatric	Р	P	₽	Р	Р	P	BMDC	Note 2,3,4,6,9,10
Imaging & Other	SmallOrgan (Note 1)	,							
	Neonatal Cephalic	_							
	Adult Cephalic				<u> </u>				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
,	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)							.	
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)					l			

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
		Note 21	syngo Auto follicle

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510(k)	Number	(if known	١.
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Device Name:

EV9F4 Curved Array Mechanical 3D/4D Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic				,				•
	Fetal	Р	P	Р		P	P	BMDC	Note 2,3,4,5,6,9,10,12, 19,
	Abdominal								ı
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric				<u></u>				·
lmaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic	Р	P	Р		Р	Р	BMDC	Note 2,3,4,5,9,10
	Adult Cephalic								
	Trans-rectal	Р	Р	Р		Р	Р	BMDC	Note 2,3,4,5,9,10,19
	Trans-vaginal	Р	Р	Р		Р	P	BMDC	Note 2,3,4,5,9,10,12,19, 21
	Trans-urethral			-					
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)							,	
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac				ļ		<u> </u>		
	Other (Specify)	<u></u>			<u> </u>	<u> </u>			
Peripheral	Peripheral vessel								
Vessel	Other (Specify)				I	j			

N = new indication; P = previously cleared K121699

For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
3-Scape 3D Imaging	Note 15	CartoSound Communication
For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Stress Echo Imaging	Note 17	syngo fourSight TEE View
Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
	Note 21	syngo Auto follicle
	SieClear Advanced SieClear 3-Scape 3D Imaging For example: abdominal, vascular Stress Echo Imaging Axius Edge Assisted Ejection Fraction Clarify Vascular Enhancement Technology	Dynamic TCE Technology SieClear Advanced SieClear 3-Scape 3D Imaging For example: abdominal, vascular Stress Echo Imaging Axius Edge Assisted Ejection Fraction Clarify Vascular Enhancement Technology SieScape Panoramic Imaging Note 20

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510(k) <u>K123001</u>	Page 15 of

510(k) Number (if known):

Device Name:

SoundStar 10F Transducer for use with:

ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Appli	Mode of Operation								
Other (Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	. Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								· · · · · · · · · · · · · · · · · · ·
	Fetal							,	
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric				i i		,		
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)						• • • • • • • • • • • • • • • • • • • •		
	Musculo-skel. (Convent.)								<u> </u>
	Musculo-skel. (Superfic)								
	Intra-vascular	Р	Р	Р	P	Р	Р	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								·
	Cardiac Adult	Р	Р	Р	Р	Р	Р	BMDC	Note 2,8,9,13,14,15,16
Cardiac	Cardiac Pediatric	Р	P	P	Р	Р	Р	BMDC	Note 2,8,9,13,14,15,16
	Intra-vascular (Cardiac)	Р	Р	Р	P	Р	Р	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	Р	P	Р	P	Р	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)					<u> </u>		<u> </u>	
Peripheral	Peripheral vessel				<u> </u>			<u> </u>	
Vessel	Other (Specify)					<u> </u>		1	

N = new indication; P = previously cleared K121699

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.	Note 11	syngo Arterial Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
		Note 21	syngo Auto follicle

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510(k) Number (if known):

Device Name:

SoundStar eco 10F Transducer for use with: ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks1I& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)								·
	Neonatal Cephalic								
	Adult Cephalic	1		<u> </u>	<u> </u>				
	Trans-rectal				-				
	Trans-vaginal					<u> </u>			
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)		-						
	Musculo-skel. (Superfic)								
	Intra-vascular	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
	Cardiac Adult	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
Cardiac	Cardiac Pediatric	N	N	N	N	N	· N	BMDC	Note 2,8,9,13,14,15,16
	Intra-vascular (Cardiac)	N	N	N	N	N	N	вмос	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)			<u>-</u>					
	Intra-cardiac	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)					,			
Peripheral	Peripheral vessel								•
Vessel	Other (Specify)				I	1			

N = new indication; P = previously cleared

NO(E 1	For example: breast, testes, thyrold, penis, prostate, etc.	Note 11	syngo Arienai Health Package (AHP)
Note 2	Dynamic TCE Technology	Note 12	syngo Auto OB Measurements
Note 3	SieClear	Note 13	syngo Auto Left Heart (Auto LH) Technology
Note 4	Advanced SieClear	Note 14	syngo Velocity Vector Imaging Technology
Note 5	3-Scape 3D Imaging	Note 15	CartoSound Communication
Note 6	For example: abdominal, vascular	Note 16	Intracardiac Echocardiography (ICE) Imaging
Note 7	Stress Echo Imaging	Note 17	syngo fourSight TEE View
Note 8	Axius Edge Assisted Ejection Fraction	Note 18	syngo Mitral Valve Assessment (MVA)
Note 9	Clarify Vascular Enhancement Technology	Note 19	syngo fourSinght 4D imaging
Note 10	SieScape Panoramic Imaging	Note 20	Contrast Agent Imaging
		Note 21	syngo Auto follicle

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